DETAILED ACTION

CONTINUED EXAMINATIONS

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/21/2011 has been entered.

Applicant's amendment in the reply filed on 2/22/2011 is acknowledged. Claims 2-7, 9, 11, and 12 are cancelled. Claims 1, 8, 10, and 13-20 are pending. Claim10 is withdrawn. **Claims 1, 8, and 13-20 are examined on the merits**.

Any rejection that is not reiterated is hereby withdrawn.

Claim Rejections –35 USC § 112, 1st New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 8, and 13-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claims 1, 8, and 13-17 recite a composition comprising a tablet for oral administration comprises certain percentages of deep sea fish and rooibos. However, those percentages are for topical administration, not for oral administration. For instance, in the specification, page 4, 2nd

paragraph, it is stated "The above ranges are suitable for oral administration. However, for topical administration, an appropriate daily dosage of the extract of the deep sea fish will usually be obtained if a lotion to be administered two times pr. day comprises 0.25 - 2.0, such as 0.5 - 1.5, for example 1.0 wt% of the extract of a deep sea fish". Further more, on page 4, 5th paragraph, it is stated "The above ranges are suitable for oral administration. However, for topical administration, an appropriate daily dosage of the extract of the rooibos (aspalathus linearis) will usually be obtained if a lotion to be administered two times pr. day comprises 2 - 20, such as 1 - 15, for example 2 - 12, e.g. 3 - 10, such as 5 - 8 wt% of the Rooibos extract". Thus, the specification fails to provide any support regarding the description of a composition comprising a tablet for oral administration comprising certain percentages of deep sea fish and rooibos as recited in claims 1, 8, and 13-17. Therefore, it is not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, Applicant had possession of the tablet for oral composition comprising certain percentages of deep sea fish and rooibos as recited in claims 1, 8, and 13-17 in the invention. Thus, the subject matter as claimed in claims 1, 8, and 13-17 is a new matter that needs to be cancelled.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 8, and 13-17 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Tokumaru (JP 09191852 A), in view of Kujiyou (JP 07039339 A).

Tokumaru et al teach the health foods contain fermented milk as a main ingredient, Ca salts and oligosaccharides as active ingredients, and .gtoreq.1 foods selected from nucleic acid foods, shark cartilage, Chlorella, collagen, Agaricus blazei, champignon ext., mulberry tea, Tochu (Eucommia ulmoides) tea, Tochu-ginseng tea, Tencha, multivitamins, Fe, soybean peptides, Angelica keiskei, Aloe, and Gymnema as supplementary ingredients (see Abstract). Tokumaru et al teach lyophilization powder of a kefir contains 100g cow's milk calcium powder; 0.5 g chain oligosaccharide powder (thus fillers and coating agents); 4 g DNA powder extract; powder of a 1.5 g shark fin extract (thus a solid deep sea fish extract, thus an active components, thus 1.5/ (100 + 0.5 + 4 + 1.5 + 0.2 + 4.5) = 1.5/110 = 1.3%, thus falls into the claimed range of 0.25-2% in claim 1; about 0.5-1.5% in claim 13; and about 1.0% in claim 14); the end of 0.2 g angelica dried powder, and health food obtained 4.5 g (thus ancillary agents) [0047]. Tokumaru et al teach the health food of this invention may be in the form of a tablet (thus contains one or more fillers or ancillary agents conventionally used in the formulation of tablets pharmaceutical composition, thus for oral administration), etc [0035]. Tokumaru et al teach with Eucommi-ulmoides bark and ginseng radix tea, effects such as cosmetics, recovery from fatigue, aging prevention, and beautiful skin effect are given (thus daily dosage for cosmetic treatment of the skin) [0042] (machine translation is attached).

Tokumaru et al do not teach the incorporation of rooibos extract; neither do Tokumaru et al teach the claimed amount of rooibos extract.

Kujiyou teaches the method for preparation Rooibos Tea (Aspalathus linearis, REDBUSH tea, ROOIBOSCHTEA, taste tea, Leguminosae) extract comprises selecting fresh or dry branches and leaves of Rooibos tea, fermented product or mixture thereof as raw material, and extracted with 2-200 wt. times of water solvent with pH of 7-12 at 40-100.degree.C for 15min to 4hr to obtain Rooibos tea extract The extract obtained by this method has high content of polyethylene phenol materials such as flavonoid and tannin, and can be used as materials of beverage or health food. The pH of the extractive solution is regulated with base such as sodium hydroxide and sodium bicarbonate or basic salt. The Rooibos tea extract has effects in caring skin, strengthening body, relieving allergy, skin and viscera diseases, scavenging free radicals, resisting aging, resisting oxidation, and preventing cancer (thus an active component) (see Abstract). Tokumaru et al teach the rooibos tea extract is extremely excellent in palatability, and has wide range of fields such as health food and drink [0030] (machine translation is attached).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate rooibos tea from Kujiyou into the health food of Tokumaru et al since Kujiyou teaches rooibos tea extract is extremely excellent in palatability, and has wide range of fields such as health food. It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate rooibos tea from Kujiyou into the health food of Tokumaru et al since Kujiyou teaches the Rooibos tea extract has effects in caring skin, and resisting aging effect. Therefore, one of the ordinary skills in the art

would have been motivated to incorporate rooibos tea from Kujiyou into the health food of Tokumaru et al to enhance its aging prevention, and skin-beautifying effect.

With regard to the claimed amount of rooibos, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar

proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the claimed percentage of rooibos, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of rooibos. For instance, the amount of rooibos extract in the health food could be determined by the concentration of the extract, the extraction method of the extract, or the harvest season of the plant. The amount of rooibos extract in the health food could also be varied according to the skin condition of the subject.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 18-20 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Strumor et al (US 6,149,939), in view of Kato et al (JP 05246866 A).

Strumor et al teach a tablet (thus for oral administration, thus containing one or more fillers or ancillary agents conventionally used in the formulation of pharmaceutical composition) for aiding memory comprising 200 mg of shark cartilage (thus a solid extract of a deep sea fish comprising protein, thus as active component) and 16 other components with total weight of the

tablet at 2281 mg (thus 200/2281 = 8.8%, thus about 10%, thus about 12.40%) (col 8, Example II).

Strumor et al do not teach the incorporation of rooibos, neither do Strumor et al teach the claimed amount of rooibos or deep sea fish extract.

Kato et al teach a therapeutic agent for stimulating cerebral metabolism and improving cerebral function contains Aspalathus linearis extract as effective component. The extract is obtained by extracting the leaves or stems of Aspalathus linearis belonging to Leguminosae with water and/or an organic solvent such as methanol, ethanol or acetone to get the Extract. The extract is mixed with conventional medicinal carrier, excipient, binder (thus one or more fillers or ancillary agents), and diluent, and prepared into granule, powder, hard capsule, elastic capsule, syrup, suppository, and injection. The preparation containing Aspalathus linearis extract can be used for stimulating brain metabolism of mammals including human, improving memory and brain function, treating or improving brain and nervous diseases such as senile dementia and Parkinson disease, without side effect (see Abstract) (machine translation is attached).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate rooibos tea from Kato et al into the tablet of Strumor et al since Kato et al teach rooibos tea extract is effective in improving memory. Therefore, it would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate rooibos tea from Kato et al into the tablet of Strumor et al to enhance its memory aiding effect.

With regard to the claimed amount of shark cartilage, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. For instance, the amount of shark cartilage extract in the tablet could be determined by the concentration of the extract, or the extraction method of the extract.

With regard to the claimed amount of rooibos extract, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar

proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the claimed percentage of rooibos extract, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of rooibos extract because concentrations of the claimed rooibos extract are art-recognized result effective variables because they have the ability to improve memory, which would have been routinely determined and optimized in the pharmaceutical art.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejections.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Primary Examiner, Art Unit 1655